

Applicants: Gregory B. Wilson et al.
Serial No.: 09/776,010
Filed: February 2, 2001
Page 2

REMARKS

Claims 32, 33, 36-40, 42-43, and 46-47 are pending in the subject application.

Claim Rejections under 35 U.S.C. §103(a)

In the March 24, 2006 Office Action, the Examiner rejected claims 32-33, 36-40, 42, 43, 46 and 47 under 35 U.S.C. §103(a) as allegedly unpatentable over Wilson et al. (Patent No. 4,816,563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86).

In response, applicants respectfully traverse the Examiner's rejection.

Applicants' claimed invention provides a fluid consisting of a colostrum of a human herpesvirus-6A-immunized or a human herpesvirus-6B-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat. This invention also provides a pharmaceutical composition comprising the instant colostrum, and methods of using this fluid to treat chronic fatigue syndrome.

The Examiner alleged that Wilson et al. teach both the method for purification of antigen-specific transfer factor (TF) and provide motivation to remove other substances from the TF composition. The Examiner also alleged that Ablashi et al. teach that HHV6A and HHV6B are of particular interest in that HHV6A- and HHV6B-specific TF can be used for treating Chronic Fatigue Syndrome. The Examiner also alleged that Ablashi et al. teach a mechanism explaining why HHV6A- and HHV6B-specific TF can be used for treating Chronic Fatigue Syndrome.

Applicants: Gregory B. Wilson et al.
Serial No.: 09/776,010
Filed: February 2, 2001
Page 3

Applicants note that Ablashi et al. do not teach HHV6A-specific and HHV6B-specific TF as the Examiner has asserted. As Ablashi et al. state at page 82 under the heading "Transfer Factor", the transfer factor taught is raised for "HHV-6, EBV and CMV live viruses." This teaching does not constitute a teaching of HHV6A-specific or HHV6B-specific TF. Indeed, Ablashi et al. in combination with Wilson et al., do not teach or suggest removing the EBV and CMV component of the TF disclosed in Ablashi et al. Moreover, Ablashi et al. in combination with Wilson et al. suggest that both EBV and HHV6 need to be controlled in treating CFS (see Ablashi et al. at page 84, first paragraph of the discussion). Specifically, Ablashi et al. state that the causative agents of CFS are not yet identified, but that active chronic viral infection, such as EBV and/or HHV-6, could play a role. Ablashi goes on to state that their TF suppressed the CFS symptoms together with the presence of HHV-6 and EBV infection, thereby improving the patient's clinical condition. In sum, Ablashi et al. in combination with Wilson et al. neither teach nor suggest all the elements of the claimed compositions or methods.

In light of this, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

The Examiner also rejected claims 32-33, 36-40, 42, 43, 46 and 47 under 35 U.S.C. §103(a) as allegedly obvious over an advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p. 29, in view of an advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 15, Fall 1997, p. 27 and EP 0143445.

In response, applicants respectfully traverse the Examiner's rejection.

Again applicants' claimed invention provides a fluid consisting

Applicants: Gregory B. Wilson et al.
Serial No.: 09/776,010
Filed: February 2, 2001
Page 4

of a colostrum of a human herpesvirus-6A-immunized or a human herpesvirus-6B-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat. This invention also provides a pharmaceutical composition comprising the instant colostrum, and methods of using this fluid to treat chronic fatigue syndrome.

Applicants note that the News Report No. 17 discusses a proposed product named "Immunfactor6" which may contain "transfer factors specific for various subsets" and refers to HHV6A and HHV6B. Initially, applicants note that there is no indication from News Report No. 17 that such a product was ever made, and the Examiner has not shown such. Applicants further note that News Report No. 15 discusses "Immunfactor" which is directed against 12 viruses including HHV6. EP 0143445 discusses a method of creating transfer factor from the colostrums of immunized bovinds. Pertinently, the cited advertisements in combination with EP 0143445 teach, at most, a non-specific transfer factor product raised for multiple viruses. Combined, they do not teach the elements of (i) a fluid consisting of a colostrum of a human herpesvirus-6A-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat, (ii) a fluid consisting of a colostrum of a human herpesvirus-6B-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat, or (iii) a method for treating CFS using such compositions. In sum, the two advertisements and EP 0143445 in combination neither teach nor suggest all the elements of the claimed products or methods. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

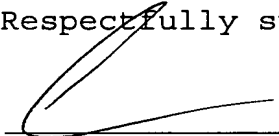
Applicants: Gregory B. Wilson et al.
Serial No.: 09/776,010
Filed: February 2, 2001
Page 5

Summary

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, apart from the \$510.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Communication. If any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Alan J. Morrison
Reg. No. 37,399

9/25/06
Date